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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/447,820	05/23/95	EKINS	R

EXAMINER	
WOODWARD, M	
ART UNIT	**PAPER NUMBER**
1815	9

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DANN DORFMAN HERRELL AND SKILLMAN
SUITE 720
1601 MARKET STREET
PHILADELPHIA PA 19103-2307

DATE MAILED: 09/02/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

(Paper No 8)

☒ Responsive to communication(s) filed on MARCH 21, 1997 (Paper Nos 5, 7) & JUNE 12, 1997.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-8 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☒ received in Application No. (Series Code/Serial Number) 07/460 878.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Applicant's arguments filed March 21, 1997 and June 12, 1997 have been fully considered but they are not persuasive.

Applicant's arguments concerning his right to foreign priority are noted. However, applicant's declaration is not in compliance with the requirements for such priority. A new declaration referencing the PCT application as well as the British application should be submitted. Until such time as a proper declaration is submitted the rejections relying on WO 88/01058 will be relied upon.

The rejection of claims 1-3 under the judicially created doctrine of double patenting over claims 1-17 of U. S. Patent No. 5,432,099 is withdrawn in view of the filing of a Terminal Disclaimer.

The rejection of claims 1-3 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,432,099 in view of Chen et al. (4,385,126) is withdrawn in view of the filing of a Terminal Disclaimer.

Claims 1-3 are again rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Ekins et al. (1989).

Claims 1 and 2 are again rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Ekins (WO 88/01058).

Claim 3 is again rejected under 35 U.S.C. § 103 as being unpatentable over Ekins (WO 88/01058) in view of the commercial availability of the Bio-Rad Lasersharp MRC 500.

Claims 1 and 2 are again rejected under 35 U.S.C. § 103 as being

unpatentable over the combined teachings of Ekins (WO 84/01031) and Chen et al. (US 4,385,126).

Claims 1-8 are rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Ekins (WO 84/01031) and Chen et al. (US 4,385,126) as applied to claims 1 and 2 above, and further in view of the commercial availability of the Bio-Rad Lasersharp MRC 500.

Applicant's traversal of these rejections asserts that WO 84/01031 fails to teach the advantage of employing 0.1 V/K moles of binding agent and that Chen et al. cannot properly be combined with WO 84/01031 as it is directed toward a fundamentally different assay.

Applicant's argument regarding WO 84/01031 attempts to confine the teachings of WO 84/01031 to only that which is explicitly stated. Applicant's traversal fails to take into consideration that a person of ordinary skill in the art at the time the invention was made would have analyzed the teachings of WO 84/01031 thoroughly. Such an analysis would have included a complete characterization of the physicochemical aspects of the assay therein described. It is quite clear that one of ordinary skill in the art at the time the invention was made would have sought, especially in view of the explicit teachings in WO 84/01031, to minimize the amount of binding agent so as to preclude significant alteration of the concentration of analyte in the sample. The exact value at which significant alteration is deemed to occur is a matter of choice. In choosing a particular value for the amount of binding agent present one of ordinary skill in the art would certainly take into account the concentration range over which analyte

concentrations would be measured and choose a value compatible therewith. To argue to the contrary as does applicant clearly ignores the level of skill of the person of ordinary skill in the art.

Attorney argument relying on *In re Burt* (148 USPQ 548 (CCPA 1966)) is moot in view of a demonstrated correlation between the facts therein and those present in the instant application.

Applicant's arguments concerning the format of the Chen et al. reference are not on point as the format is not at issue. Chen et al. is pertinent for its teachings regarding calibration and quality control. These teachings are relevant regardless of assay format and are fundamental to any well controlled analyte assay. Certainly, would of ordinary skill in the art at the time the invention was made would have been aware of and taken into account such teachings when seeking to optimize the invention of WO 84/01031.

Applicant points to such teachings at pages 7 and 8 of the response of March 21, 1997 and attempts to dismiss them by asserting that such teachings are confined to Chen et al.

It is noted that at page 7 of the response of March 21, 1997 that applicant admits that dual labelling is "reasonably well known in the art, but for quite different reasons than its use in the present invention."

Applicant states at page 10

> In other words, the double label according to Chen et al. is used specifically to ensure that the amount of immobilized receptor is constant, and to compensate for possible variations in the measurement efficiency.

As to why one would not also seek to do this in the WO 84/01031 assay is left unstated by applicant. Moreover, by quantifying the amount of immobilized

receptor present one can more accurately determine fractional occupancy . In the WO 84/01031 assay a determination of the amount of receptor immobilized is made independent of analyte measurement. Clearly, being able to measure the amount of immobilized receptor in each assay is advantageous over determining the bulk properties of immobilized receptor as is done in WO 84/01031. One cannot calculate fractional occupancy without such a measurement.

It would appear then, that the issue becomes whether or not a person of ordinary skill in the art seeking to practice the invention of WO 84/01031 would have found it obvious to have made a determination of the amount of receptor immobilized differently than as is taught therein. In WO 84/01031 the binding capacity of the solid phase is indirectly estimated by Scatchard analysis. Clearly, a direct determination of immobilized receptor would obviate any errors associated with a Scatchard analysis and would thus be preferable. Thus, one would have had clear motivation to label the receptor and to have determined the amount immobilized.

It is further noted that a determination of obviousness does not require that the motivation for making the invention be the same as that suggested or argued by applicant (*In re Dillon*, 16 USPQ2d 1897, (Fed. Cir. 1990))

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. If a notice of appeal and the appeal fee set forth in 37 CFR 1.17(e) were filed prior to or with the payment of the fee set forth in 37 CFR 1.17(r), the payment of the fee set forth in 37 CFR 1.17(r) by applicant will be construed as a request to dismiss the appeal and to continue prosecution under 37 CFR 1.129(a). In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MP Woodward whose telephone number is (703) 308-3890. The examiner can normally be reached on Monday-Friday from 7:30 AM to 5:00 PM. In the event that the examiner does not personally answer the telephone his voice mail will provide the necessary instructions.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311.

Currently a plurality of official and unofficial fax lines are available. However, changes in fax location occur with frequency. Please contact the examiner to obtain the currently operative fax numbers.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 1, 1997

MICHAEL P. WOODWARD
PRIMARY EXAMINER
GROUP 1800